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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98D-0264, 98D-0265, et al.]

Food and Drug Administration Modernization Act of 1997; Establishment of Public Dockets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is establishing a series of public dockets containing information on the implementation of the Food and Drug Administration Modernization Act of 1997 (Modernization Act). This action is intended to ensure that information submitted to FDA on the implementation of the Modernization Act is available to all interested persons in a timely fashion.

ADDRESSES: The public dockets are located in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The public dockets may be accessed directly under the docket numbers provided in the list below, and they are also posted on the agency's Internet World Wide Web (WWW) site at "<http://www.fda.gov/ohrms/dockets>".

FOR FURTHER INFORMATION CONTACT:

Nancy E. Derr, Center for Drug Evaluation and Research (HFD-5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5400;

Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6210;

Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-2974; or

George A. Mitchell, Center for Veterinary Medicine (HFV-6), Food and Drug Administration,
7500 Standish Pl., Rockville, MD 20855, 301-827-5587.

SUPPLEMENTARY INFORMATION: On November 21, 1997, the President signed the Modernization Act into law (Pub. L. 105-115). The Modernization Act provides for the reauthorization of the Prescription Drug User Fee Act of 1992, codifies many FDA initiatives undertaken in recent years under the Administration's Reinventing Government Program, and implements certain other reforms of FDA processes.

FDA has received numerous recommendations on how the agency should implement various Modernization Act provisions for which dockets have not yet been established. To provide timely public access to these recommendations, FDA is establishing a series of public dockets through which interested persons can have access to these recommendations and other information submitted to FDA. Each docket contains information pertaining to a specific section of the Modernization Act and may be accessed directly under the docket numbers provided in the list below. FDA expects to place submissions containing recommendations on how the agency should implement the Modernization Act in one of these public dockets, or in a new docket created for the specific provision addressed in the recommendations. These dockets are in addition to those already established in connection with implementation of other provisions of the Modernization Act, i.e., dockets assigned to the Modernization Act-related notices, guidances, or rules.

The following is a list of dockets that FDA is establishing at this time to provide access to information submitted relating to the implementation of specific provisions of the Modernization Act. The list includes the section number of the Modernization Act, the title of the docket, and the docket number.

Section No.	Docket Title	Docket No.
111	Pediatric Studies of Drugs	98D-0265
112	Fast Track Products	98D-0267
113	NIH Data Bank—Clinical Trials for Serious Diseases	98D-0293
114	Health Care Economic Information	98D-0468
118	Data Requirements for Drugs and Biologics	98D-0264
121	Positron Emission Tomography (PET)	98D-0266
122	Radiopharmaceuticals	98D-0372
127	Pharmacy Compounding	98D-0272
216	Six-Year Use of Data	98D-0466

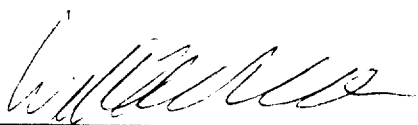
Section No.	Docket Title	Docket No.
406	Agency Plan for Statutory Compliance	98N-0339

From time to time, FDA may establish dockets on other Modernization Act provisions but does not intend to separately announce the creation of such dockets. Instead, a list of the Modernization Act dockets will be maintained on the agency's Internet WWW site at "<http://www.fda.gov/ohrms/dockets>". The dockets created in connection with specific notices, guidances, or rules published in the **Federal Register** are also listed at this site.

The public dockets are available for public review in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 22, 1998

July 22, 1998



William K. Hubbard
Associate Commissioner for Policy Coordination

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